



December 5, 2008

P. V. Shah  
USEPA Headquarters  
Ariel Rios Building  
1200 Pennsylvania Avenue, N. W.  
Mail Code: 7505P  
Washington, DC 20460 - 0001

sent via e-mail: shah.pv@epa.gov

Re: Request for Exclusive Use Protection for Aromatic 150 & Aromatic 200 Fluids

Dear P.V. Shah:

This is a request by ExxonMobil Chemical Company (ExxonMobil) for exclusive use protection for data submitted to establish tolerance exemptions for the inert ingredients "Aromatic 150 and Aromatic 200 Fluids" as used in pesticide formulations.<sup>1</sup> ExxonMobil believes that these substances are entitled to exclusive use protection for the following reasons:

1. On January 24, 2006 and February 1, 2006, EPA approved tolerance exemptions for Aromatic 150 and Aromatic 200 Fluids, publishing the regulations at 40 C.F.R. §180.910 and 40 C.F.R. § 180.930, respectively.
2. These tolerance exemptions are the original tolerance exemption regulations approved by EPA for Aromatic 150 and Aromatic 200 Fluid. EPA had never before issued tolerance exemptions for Aromatic 150 and Aromatic 200 Fluids.
3. In order to support these tolerance exemptions, ExxonMobil submitted substantial data on both Aromatic 150 (see Appendix 1 to this letter) and Aromatic 200 (see Appendix 2) using the PR-86-5 format and the petition process as required for new inert ingredients. This was the first time these data had been submitted to EPA.
4. FIFRA § 3(c)(1)(F)(i) provides that data submitted to support the "original registration" of a pesticide are entitled to exclusive use protection for a period of ten years.
5. FFDCA § 408(i)(2) provides that data submitted in support of a tolerance or exemption shall be entitled to exclusive use to the same extent provided by Section 3 of FIFRA. Therefore, just as data supporting the original registration of an active ingredient are entitled to exclusive use under FIFRA, data supporting the original

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<sup>1</sup> Aromatic 150 Fluid, C10-C11 Rich Aromatic Hydrocarbon Fluid  
Aromatic 200 Fluid, C11-C12 Rich Aromatic Hydrocarbon Fluid

tolerance regulation or exemption for a pesticide inert ingredient are also entitled to ten years of exclusive use.

6. The intention of FIFRA § 3(c)(1)(F)(i) is to provide exclusive use protection for the data required for the initial EPA approval of the safety of a pesticide active ingredient. By analogy, the exclusive use protection provided by FFDCA § 408(i)(2) is intended to apply to the data required for the initial EPA approval of a tolerance regulation or exemption for a specific pesticide active or inert ingredient.
7. Because the regulations establishing an exemption from tolerance for Aromatic 150 and Aromatic 200 Fluids, published at 40 CFR 180.910 and 40 CFR 180.930, are the first regulations establishing the safety of these ingredients, the data supporting these regulations, listed in Appendix 1 and Appendix 2, are entitled to 10 years of exclusive use protection. Therefore, ExxonMobil requests that EPA grant exclusive use protection for these data under FFDCA 408(i).

Can you please confirm for me that the data in Appendix 1 and 2 will be placed on the data submitters list to be published by EPA for inert ingredients, and that it will be listed as entitled to exclusive use protection? Please telephone me at 281-870-6093 if there are any questions concerning this matter.

Thank you very much.

Sincerely,



Arlean M. Rohde  
Intermediates, Fluids Regulatory Affairs  
CORP/EMCC/W3-222  
Phone: (281) 870-6093  
Cell: (281) 413-4196  
e-mail: arlean.m.rohde@exxonmobil.com

## Appendix I

### Data Submitted to Support The Petition for Exemption From Tolerance for Aromatic 150 Fluid (also known as Solvesso™ 150 Fluid)

MRID No.	Title
46398901	Risk Assessment in Support of Tolerance Exemption Reassessment for ExxonMobil's Aromatic 150 Fluid (Guideline: Not Applicable)
46398902	IUCLID Database for Aromatic 150 Fluid (Guideline: Not applicable)
46398903	Toxicology Laboratory Report on Aromatic 150 Fluid <ul style="list-style-type: none"> <li>EMBSI 1990a. Primary Dermal Irritation Study in the Rabbit. Study No. 252304. (Guideline: 404)</li> </ul>
46398904	Toxicology Laboratory Report on Aromatic 150 Fluid <ul style="list-style-type: none"> <li>EMBSI 1990b. Ocular Irritation in the Rabbit. Study No. 172113. (Guideline: 405)</li> </ul>
46398905	Toxicology Laboratory Report on Aromatic 150 Fluid <ul style="list-style-type: none"> <li>EMBSI 1991. 90-Day Subchronic Oral Toxicity Study in the Rats. Study No. 188470. (Guideline: 408, FIFRA 82-1)</li> </ul>
46398906	Toxicology Laboratory Report on Aromatic 150 Fluid <ul style="list-style-type: none"> <li>EMBSI 1992. Developmental Toxicity Study in Rats. Study No. 188434 (Guideline: 414, FIFRA 83-3)</li> </ul>
46398907	Toxicology Laboratory Report on Aromatic 150 Fluid <ul style="list-style-type: none"> <li>EMBSI 1995a. Acute Oral Toxicity Study with LD50 Estimate in the Rabbit. Study No. 195302. (Guideline: 401)</li> </ul>
46398908	Toxicology Laboratory Report on Aromatic 150 Fluid <ul style="list-style-type: none"> <li>EMBSI 1995b. Acute Inhalation Toxicity Study in Rats. Study No. 195316. (Guideline: 403)</li> </ul>
46398909	Toxicology Laboratory Report on Aromatic 150 Fluid <ul style="list-style-type: none"> <li>EMBSI 1995c. Acute Dermal Toxicity Study with LD50 Estimate in the Rabbit. Study No. 195307. (Guideline 402)</li> </ul>

MRID No.	Title
46398910	<b>Toxicology Laboratory Report on Aromatic 150 Fluid</b> <ul style="list-style-type: none"> <li>• Product Investigations, Inc. 1987. Evaluation of the Skin Irritating and Sensitizing Capabilities in Humans with or without UV Irradiation of Contact Sites. Study No. 298124. (Guideline: GCP)</li> </ul>
46398911	<b>Toxicological Profile and Risk Assessment for Naphthalene: Assessment in Support of Tolerance Exemption Reassessment for Aromatic 150 and Aromatic 200 Fluids (Guideline: Not Applicable)</b>
46369812	<b>Dietary Risk Assessment of Aromatic 100 Fluid, Aromatic 150 Fluid, and Aromatic 200 Fluid Associated with Their Use as Inert Ingredients in Agricultural Products. (Guideline: Not Applicable)</b>
46369813	<b>Residential (Non-Dietary) Risk Assessment of Aromatic 100 Fluid, Aromatic 150 Fluid, and Aromatic 200 Fluid Associated with Their Use as Inert Ingredients in Consumer Pesticide Products (Guideline: Not applicable)</b>

## Appendix 2

### Data Submitted to Support The Petition for Exemption From Tolerance for Aromatic 200 Fluid (also known as Solvesso™ 200 Fluid)

MRID No.	Title
46396901	Risk Assessment in Support of Tolerance Exemption Reassessment for ExxonMobil's Aromatic 200 Fluid (Guideline: Not Applicable)
46396902	IUCLID Database for Aromatic 200 Fluid (Guideline: Not applicable)
46396903	Toxicology Laboratory Report on Aromatic 200 Fluid <ul style="list-style-type: none"> <li>• EMBSI 1993. Acute Inhalation Toxicity in Rats. Study No. 140415. (Guideline: 403)</li> </ul>
46396904	Toxicology Laboratory Report on Aromatic 200 Fluid <ul style="list-style-type: none"> <li>• EMBSI 1997a. Acute Inhalation Toxicity Study in Mice. Study No. 124616a. (Guideline: 403)</li> </ul>
46396905	Toxicology Laboratory Report on Aromatic 200 Fluid <ul style="list-style-type: none"> <li>• EMBSI 1997b. Upper Airway Sensory Irritation Study in the Mouse. Study No. 155951. (Guideline: Not applicable)</li> </ul>
46396906	Toxicology Laboratory Report on Aromatic 200 Fluid <ul style="list-style-type: none"> <li>• EMBSI 1997c. Acute Inhalation Toxicity Study in Rats. Study No. 124616. (Guideline: 403)</li> </ul>
46396907	Toxicology Laboratory Report on Aromatic 200 Fluid <ul style="list-style-type: none"> <li>• EMBSI 1990. Primary Dermal Irritation in the Rabbit. Study No. 252404. (Guideline: 404)</li> </ul>
46396908	Toxicology Laboratory Report on Aromatic 200 Fluid <ul style="list-style-type: none"> <li>• EMBSI 1991d. 90-Day Subchronic Oral Toxicity Study in Rats. Study No. 188470. (Guideline: 408: FIFRA 82-1)</li> </ul>
46396909	Toxicology Laboratory Report on Aromatic 200 Fluid <ul style="list-style-type: none"> <li>• EMBSI 1991a. Acute Oral Toxicity Test with LD50 Estimation in the Rat. Study No. 188402. (Guideline: 401)</li> </ul>

<b>MRID No.</b>	<b>Title</b>
<b>46396910</b>	<b>Toxicology Laboratory Report on Aromatic 200 Fluid</b> <ul style="list-style-type: none"> <li>• <b>EMBSI 1991b. In Vivo Mammalian Bone Marrow Micronucleus Assay: Oral Gavage Dosing Method. Study No. 188430. (Guideline 474, FIFRA 84-2)</b></li> </ul>
<b>46396911</b>	<b>Toxicology Laboratory Reports on Aromatic 200 Fluid</b> <ul style="list-style-type: none"> <li>• <b>EMBSI 1991c. Microbial Mutagenesis in Salmonella Mammalian Microsome Plate Incorporation Assay. Study No. 188425. (Guideline 471, FIFRA 84-2)</b></li> </ul>
<b>46396912</b>	<b>Toxicology Laboratory Reports on Aromatic 200 Fluid</b> <ul style="list-style-type: none"> <li>• <b>EMBSI 1992. Developmental Toxicity Study in Rats. Study No. 188434 (Guideline: 414, FIFRA 83-3)</b></li> </ul>
<b>46396913</b>	<b>Toxicology Laboratory Reports on Aromatic 200 Fluid</b> <ul style="list-style-type: none"> <li>• <b>Industrial Bio-Test Laboratories 1975. Acute Oral (rats). Dermal (Rabbits), Inhalation (rats, mice, guinea pigs) and Ocular Irritation (rabbits) Toxicity Study. Study No. 29957. (Guideline: Not available).</b></li> </ul>
<b>46396914</b>	<b>Toxicology Laboratory Reports on Aromatic 200 Fluid</b> <ul style="list-style-type: none"> <li>• <b>Product Investigation, Inc. 1987. Evaluation of the Skin Irritating and Sensitizing Capabilities in Humans with or without UV Irradiation of Contact Sites. Study No. 298124 (Guideline: GCP)</b></li> </ul>
<b>46396915</b>	<b>Toxicological Profile and Risk Assessment for Naphthalene: Assessment in Support of Tolerance Exemption Reassessment for Aromatic 150 and Aromatic 200 Fluids (Guideline: Not Applicable)</b>
<b>463690-16</b>	<b>Dietary Risk Assessment of Aromatic 100 Fluid, Aromatic 150 Fluid, and Aromatic 200 Fluid Associated with Their Use as Inert Ingredients in Agricultural Products. (Guideline: Not Applicable)</b>
<b>463690-17</b>	<b>Residential (Non-Dietary) Risk Assessment of Aromatic 100 Fluid, Aromatic 150 Fluid, and Aromatic 200 Fluid Associated with Their Use as Inert Ingredients in Consumer Pesticide Products (Guideline: Not applicable)</b>